FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
DoubleTree by Hilton Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, Maryland
May 10, 2012

DRAFT AGENDA

The committee will discuss the safety and efficacy of new drug application (NDA) 22–529, lorcaserin hydrochloride Tablets, sponsored by Arena Pharmaceuticals, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) of equal to or greater than 30 kilograms (kg) per square meter, or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related co-morbidities.

8:00 a.m.	Call to Order and Introduction of Committee	**Abraham Thomas, M.D., M.P.H., FACP** Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	**Paul T. Tran, R.Ph** Designated Federal Officer, EMDAC
8:15 a.m.	Introduction/Background	**Eric C. Colman, M.D.** Deputy Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	**SPONSOR PRESENTATIONS**	**Arena Pharmaceuticals, Inc.**
	Introductory Remarks	
	Clinical Study Designs and Patient Baseline Characteristics	
	Efficacy Results and Clinical Perspective	
	Clinical Safety Results	
	Preclinical Studies	
	Preclinical Safety: Relevance to Human Risk	
	Concluding Remarks	
10:00 a.m.	Clarifying Questions from Committee	
10:15 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

10:30 a.m.	**FDA PRESENTATIONS**
	Lorcaserin Receptor Pharmacology
	Carcinogenicity Assessment of Lorcaserin in Rodents
	Clinical Presentation of Efficacy and Safety
12:15 p.m.	Clarifying Questions from the Committee
12:30 p.m.	**LUNCH**
1:30 p.m.	Open Public Hearing
2:30 p.m.	Questions to the Committee and Committee Discussion
3:15 p.m.	**BREAK**
3:30 p.m.	Questions to the Committee and Committee Discussion
5:00 p.m.	**ADJOURNMENT**